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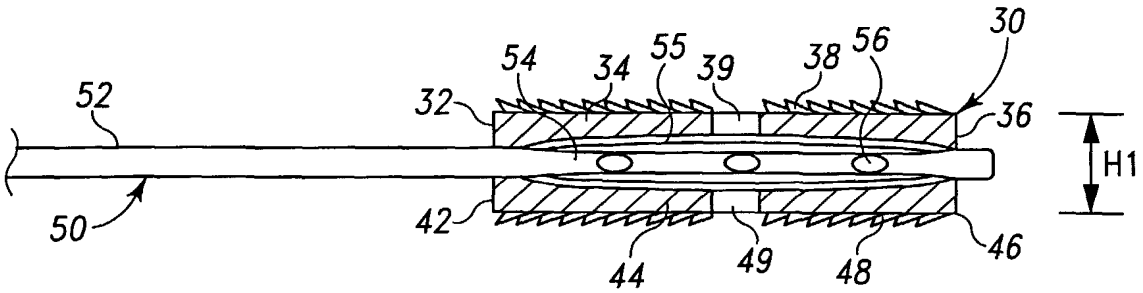

(57) Abstract: Expandable devices (30) include a body defining a hollow interior (40) for receiving distal portion (54) of a delivery instrument (50). The expandable devices are collapsed on the distal portion of the delivery instrument for delivery to the operative site within a vertebral body. Upon delivery of the collapsed expandable devices to the operative site, the distal portion of the delivery instrument is enlargeable to expand the expandable device in situ for implantation at the operative site.

WO 2004/047689 A1

SYSTEMS AND TECHNIQUES FOR INTRAVERTEBRAL SPINAL STABILIZATION WITH EXPANDABLE DEVICES

Cross-Reference to Related Application:

This application claims the benefit of the filing date of Provisional Application Ser. No. 60/428,061 filed on November 21, 2002.

BACKGROUND

Spinal deformities and injuries can require intravertebral stabilization to restore fractured or deformed vertebral body to a desired condition. Intravertebral stabilization can include the intravertebral insertion and expansion of a balloon to compact cancellous bone tissue and create an intravertebral void. Cement material can then be placed in the intravertebral void. Other techniques include intravertebral placement and expansion of mechanical expansion instruments to reduce vertebral fractures, and the subsequent removal of the instrument followed by placement of bone cement. In either case, post-reduction support of the vertebra can be provided by bone cement placed in a void formed in the vertebral body.

Intravertebral reduction with balloons and instruments can result in loss of support for the reduced vertebra when the balloon or instrument is removed to accommodate placement of material in the void created. Further, expansion or enlargement of balloons and expandable instruments in the compressible cancellous bone material can provide inconsistent results since the bone material can influence the direction and degree of expansion. Vertebroplasty techniques which include the injection of bone filler into the vertebral body can require the bone filler to be injected under high pressures with low viscosity, increasing the difficulty in controlling and targeting the filler material into the desired areas within the vertebral body.

There remains a need for additional improvements in instruments and techniques for intravertebral spinal stabilization which address these deficiencies, among others.

SUMMARY

In one aspect, a method for intravertebral reduction, comprises: accessing a vertebral body; forming an access passage into the vertebral body; delivering an expandable device through the passage into the vertebral body in an unexpanded condition; expanding the expandable device in the vertebral body with an expandable element; removing the expandable element; and placing bone filler material within the expanded expandable device.

In another aspect, a method for intravertebral reduction, comprises: accessing a vertebral body; forming an access passage into the vertebral body; delivering an expandable device through the passage into the vertebral body in an unexpanded condition; expanding the expandable device with an expandable element in the expandable device to restore a vertebral body height; removing the expandable element; and maintaining the restored vertebral height device with the expanded expandable device.

In a further aspect, a system for intravertebral reduction includes a delivery instrument with an expandable element along a distal portion thereof. The system further includes an expandable device including a cavity. The expandable device is removably mountable to the expandable element with the expandable element in the cavity and each of the expandable device and the expandable element in an unexpanded condition. The expandable device is deliverable to an intravertebral space in the unexpanded condition and thereafter expandable with expansion of the expandable element to compress cancellous bone in the intravertebral space.

In another aspect, a system for intravertebral reduction includes a delivery instrument with a non-rigid expandable element along a distal portion thereof. The system further includes an expandable device with a cavity between substantially rigid first and second portions. The expandable device is structured for positioning in an intravertebral space. When expandable element is positioned in the cavity it is expandable to move the first and second portions away from one another and compress cancellous bone in the intravertebral space.

These and other aspects are also presented in the following description.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a sectional view of a collapsed expandable device and delivery instrument.

Fig. 2 is the expandable device and delivery instrument of Fig. 1 in an expanded condition.

Figs. 3 and 4 are a plan view and an elevation view in partial section, respectively, of a spinal column segment having a pair of expandable devices and delivery instruments positioned in an intravertebral space in an unexpanded condition.

Figs. 5 and 6 are a plan view and an elevation view in partial section, respectively, with the expandable devices and delivery instruments of Figs. 3 and 4 in an expanded condition in the intravertebral space.

Figs. 7 and 8 are a plan view and an elevation view in partial section, respectively, with expanded expandable devices of Figs. 5 and 6 in the intravertebral space and the delivery instruments removed.

Figs. 9 and 10 are a plan view and an elevation view in partial section, respectively, of a spinal column segment and another embodiment pair of expandable devices and delivery instruments positioned in an intravertebral space in an unexpanded condition.

Figs. 11 and 12 are a plan view and an elevation view in partial section, respectively, with expandable devices and delivery instruments of Figs. 9 and 10 in an expanded condition in the intravertebral space.

Figs. 13 and 14 are a plan view and an elevation view in partial section, respectively, with the expandable devices of Figs. 11 and 12 expanded in the intravertebral space and the delivery instruments removed.

Figs. 15 and 16 are a plan view in partial section and an elevation view, respectively, of a spinal column segment having an expandable device and delivery instrument positioned in an intravertebral space in an unexpanded condition.

Figs. 17 and 18 are a plan view in partial section and an elevation view, respectively, with the expandable device and delivery instrument of Figs. 15 and 16 in an expanded condition in the intravertebral space.

Figs. 19 and 20 are a plan view in partial section and an elevation view, respectively, with the expanded expandable device of Figs. 17 and 18 in the intravertebral space and the delivery instrument removed.

Fig. 21 is an end view of another embodiment expandable device.

Fig. 22 is a perspective view of another embodiment expandable device in an unexpanded configuration.

Fig. 23 is an elevation view of another embodiment expandable device in an unexpanded configuration.

Fig. 24 is an elevation view of the expandable device of Fig. 23 in an expanded configuration.

Fig. 25 is an end view of the expanded expandable device of Fig. 24.

Figs. 26A and 26B are a plan view and an elevation view in partial section, respectively, of collapsed expandable devices and delivery instruments according to another embodiment positioned in an intravertebral space of a vertebra.

Figs. 27A and 27B are a plan view and an elevation view in partial section, respectively, with expanded expandable devices and delivery instruments positioned in the intravertebral space and the vertebra reduced.

Figs. 28A and 28B are a plan view and an elevation view in partial section, respectively, with expanded expandable devices in the intravertebral space of the reduced vertebra and the delivery instruments removed.

Figs. 29A and 29B are a plan view and an elevation view in partial section, respectively, of collapsed expandable devices and delivery instruments according to another embodiment positioned in an intravertebral space of a vertebra.

Figs. 30A and 30B are a plan view and an elevation view in partial section, respectively, with expanded expandable devices and delivery instruments in the intraverebral space of and the vertebra reduced.

Figs. 31A and 31B are a plan view and an elevation view in partial section, respectively, with expanded expandable devices in the intravertebral space of the reduced vertebra and the delivery instruments removed.

Figs. 32A and 32B are a plan view and an elevation view in partial section, respectively, of collapsed expandable devices and delivery instruments according to another embodiment positioned in an intravertebral space of a vertebra.

Figs. 33A and 33B are a plan view and an elevation view in partial section, respectively, with expanded expandable devices and delivery instruments in the intravertebral space and the vertebra reduced.

Figs. 34A and 34B are a plan view and an elevation view in partial section, respectively, with expanded expandable devices in the intravertebral space of the reduced vertebra and the delivery instruments removed.

Figs. 35A and 35B are a plan view and an elevation view in partial section, respectively, with a collapsed expandable device and delivery instrument according to another embodiment positioned in an intravertebral space of a vertebra.

Figs. 36A and 36B are a plan view and an elevation view in partial section, respectively, with the expanded expandable device and delivery instrument in the intravertebral space and the vertebra reduced.

Figs. 37A and 37B are a plan view and an elevation view in partial section, respectively, with the expanded expandable device in the intravertebral space of the reduced vertebra and the delivery instrument removed.

Figs. 38A and 38B are a plan view and an elevation view in partial section, respectively, with a collapsed expandable device and delivery instrument according to another embodiment positioned in an intravertebral space of a vertebra.

Figs. 39A and 39B are a plan view and an elevation view in partial section, respectively, with the expanded expandable device and the delivery instrument in the intravertebral space and the vertebra reduced.

Figs. 40A and 40B are a plan view and an elevation view in partial section, respectively, with the expanded expandable device in the intravertebral space of the reduced vertebra and the delivery instrument removed.

Figs. 41A and 41B are elevational views of a delivery instrument with a distal expandable element in an unexpanded condition and expanded condition, respectively.

DESCRIPTION OF THE ILLUSTRATED EMBODIMENTS

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiments illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no

limitation of the scope of the invention is thereby intended. Any such alterations and further modifications in the illustrated devices, and any such further applications of the principles of the invention as illustrated herein are contemplated as would normally occur to one skilled in the art to which the invention relates.

There are provided systems and methods for positioning and deploying expandable devices in bony structures of a spinal column segment. Such systems can include instruments for delivering the expandable devices to the operative site and expanding the expandable devices in situ. When positioned for intravertebral reduction, the expandable devices provide a substantially rigid interface with the cancellous bone to direction compression forces thereto in a controlled and repeatable manner when the expandable devices are expanded. Such expansion can compress cancellous bone, provide size and/or shape restoration to bony structures, and provide immediate and long-term support of the reduced vertebra.

According to one embodiment, the delivery instrument includes a balloon catheter-type instrument having an enlargeable member adjacent a distal portion of the delivery instrument. A collapsed or unexpanded expandable device is positioned about the expandable member and secured thereto for delivery to the operative site in the unexpanded configuration. The delivery instrument can be employed in minimally invasive surgical procedures to deliver the collapsed or unexpanded expandable device to the operative site. Upon positioning the expandable device at the operative site, the distal portion of the delivery instrument is expandable to deploy and expand the expandable device at the operative site. Such deployment and expansion of the expandable device can, for example, compress cancellous bone when deployed in an intravertebral space. The expandable device can provide at least temporary support of the vertebra. Bone filler material can be positioned in a void formed at least partially by the expanded expandable device.

Delivery and expansion of the expandable device in the intravertebral space provides mechanical reduction of vertebral fractures or deformities, and post-operative mechanical support for the fractured or deformed vertebral body. Reduction of the vertebral fracture can be targeted by positioning the expandable device in a location where at least one portion of the expandable device can provide a substantially rigid interface with the cancellous bone between the device and the fracture as the device is expanded. The expandable devices can provide at least temporary maintenance of the reduction achieved through expansion while

bone filler material is positioned within the expandable device. The expandable device can be provided with one or more openings in its first and second portions, and one or more openings at its proximal and distal ends, to facilitate bony incorporation of the expandable device in the vertebral body.

The systems and methods can be employed in minimally invasive surgical approaches to the spine. Such approaches include anterior, posterior, transforaminal, lateral, oblique, transpedicular, extrapedicular, and other approaches to a vertebral body. The approaches can be uni-portal or multi-portal in nature. The approaches can be to any portion of the spinal column segment, including the sacral, lumbar, thoracic, and cervical regions. The systems and methods can be employed with any viewing system to assist in monitoring placement of the expandable devices intravertebrally. Examples of suitable viewing systems include fluoroscopic, endoscopic, microscopic, CT scan, X-ray, and naked eye visualization systems.

Referring now to Figs. 1 and 2, there is shown a first embodiment of an expandable device 30. In this embodiment, expandable device 30 includes an elongated body that includes a first portion 34 positionable toward one endplate of a vertebra and a second portion 44 positionable toward the opposite endplate of the vertebra. First portion 34 extends between a distal leading insertion end 36 and a proximal trailing end 32. Second portion 44 extends between a distal leading insertion end 46 and a proximal trailing end 42. A cavity 40 is defined between first portion 34 and second portion 44. Cavity 40 can extend between and open at distal end 36 and trailing end 32.

First portion 34 can be provided with a number of engagement members 38, and second portion 44 can also be provided with a number of engagement members 48. Engagement members 38, 48 can be in the form of teeth, spikes, ridges, threads, barbs, knurlings, protrusions, fins, and combinations thereof, for example. It is further contemplated that the outer surfaces can be smooth, or auxiliary fixation or engagement members can be provided. First and second portions 34, 44 can further include one or more openings 39, 49, respectively, to facilitate bone ingrowth.

First portion 34 and second portion 44 are movable away from one another from an unexpanded configuration, as shown in Fig. 1, to an expanded configuration, as shown in Fig. 2. In the unexpanded configuration, expandable device 30 has a height H1 between first portion 34 and second portion 44 as shown in Fig. 1. In the expanded configuration,

expandable device 30 has a height H2 between first portion 34 and second portion 44. It is contemplated that height H1 will allow expandable device 30 to be inserted, for example, in a passage drilled into a vertebral body. Height H2 can correspond to a separation distance between first and second portions 34, 44 require to reduce a vertebral fracture or deformity, or provide a desired vertebral body height, for example.

A delivery instrument 50 can be provided to move expandable device 30 from its unexpanded configuration to its expanded configuration. Delivery instrument 50 includes a proximal shaft 52 and a distal portion 54 including an expandable element 55. In the illustrated embodiment, expandable element 55 is an inflatable balloon-like structure having a collapsed configuration, as shown in Fig. 1, and an enlarged, inflated configuration, as shown in Fig. 2. Shaft 52 can be provided with a lumen through which fluid or material can be supplied through openings 56 to internal volume 57 of expandable element 55 to enlarge or inflate expandable element 55. Expandable element 55 is positionable in cavity 40 of expandable device 30 with each of the expandable element 55 and expandable device 30 in its unexpanded or collapsed configuration.

After delivery of expandable device 30 to the operative site, expandable element 55 can be inflated to provide an enlarged configuration for expandable element 55 and thus separate first and second portions 34, 44 of expandable device 30 as shown in Fig. 2. As expandable device 30 is expanded, first portion 34 and second portion 44 move away from one another and the volume of cavity 40 is increased. This expansion can compress cancellous bone and reduce vertebral fractures and/or restore a vertebral body height when device 30 is positioned intravertebrally.

One example of a suitable delivery instrument 50 includes a high-pressure balloon catheter. Shaft 52 can be rigid, semi-rigid, or flexible. Shaft 52 can be fabricated from metals, polymers, or combinations thereof. Shaft 52 can be provided with at least one lumen to allow inflation or enlargement of expandable element 55 with a biocompatible fluid, such as air or saline, for example. Other embodiments contemplate that shaft 52 includes multiple lumens to, for example, deliver bone graft, bone growth material or other suitable bone filler material into the expanded cavity 40 of an expanded device 30. It is contemplated that expandable element 55 is collapsed prior to or simultaneously with placement of the bone filler material.

In the illustrated embodiment, distal portion 54 includes a single expandable element, although multiple expandable elements are also contemplated to provide distal portion 54 with alternate enlargement characteristics. For example, distal portion 54 could include a distal expandable element and a proximal expandable element having differing heights to provide angulation between the expanded first and second portions 34, 44 of expandable device 30. In another example, distal portion 54 can include an upper expandable element and a lower expandable element which can be selectively expanded move the adjacent one of first and second portions 34, 44 while the other of the first and second portions remains stationary. In a further example, expandable element 55 expands uni-directionally to move the adjacent one of the first and second portions 34, 44 in the direction of expansion to provide intra-vertebral reduction in a targeted location.

In another embodiment, it is contemplated that distal portion 54 can be severed from shaft 52 after expansion, and post-operatively maintain expandable device 30 in an expanded condition. Accordingly, expandable element 55 can be inflated with bone growth material or other suitable bone filler material to facilitate bone growth in an intravertebral space through the expanded device 30. Expandable element 55 can be fabricated from porous material, resorbable material, or other suitable material to allow bone growth through the cavity of the expanded device.

Expandable element 55 can include a size and shape that matches the size and shape of cavity 40 in its expanded configuration. In the expanded configuration, expandable element 55 can apply a uniform expansion force along the inner wall surfaces of first portion 34 between leading end 36 and trailing end 32. If configured for bi-directional expansion as shown in Fig. 2, expandable element 55 can apply a uniform expansion force along second portion 44 between leading end 46 and trailing end 42. Expandable element 55 can be provided with any suitable overall shape including conical, frusto-conical, spherical, cubic, spherical, polygonal, ovoid, long conical, long spherical, rectangular, tapered, stepped, dog-bone shape, offset shapes and combinations thereof.

Expandable element 55 can be made from any suitable material capable of withstanding the pressure supplied to enlarge or inflate expandable element 55 in situ. Examples include various polymeric materials, including polyethylene, terephthalates, polyolefins, polyurethanes, nylon, polyvinyl chloride, silicone or other suitable material. The material

comprising expandable element 55 can be reinforced with woven or non-woven textile materials. Examples of suitable reinforcement materials include those that are polymeric and metallic in nature.

Referring now to Figs. 3 through 8, there is shown an example of a surgical technique employing the expandable devices and delivery instruments for intravertebral repair and/or restoration of a collapsed, pressure fractured or otherwise deformed vertebral body. In Figs. 3 and 4, there is shown a spinal column segment including a vertebra V1 having an upper endplate E1 and a lower endplate E2. Vertebra V1 has a reduced anterior height configuration H3 as a result of a compression fracture, collapse or other deformity or condition of one or each of the endplates E1, E2 and the vertebral body extending therebetween.

Posterior access passages 60, 62 are formed through the pedicles of vertebra V1 to access the interior of vertebral body V1. Passages 60, 62 can be formed by drilling or cutting the bony material of the pedicles to access the interior cancellous bony portion of vertebra V1. Other locations for passages 60, 62 are also contemplated, including extrapedicular approaches to vertebra V1 from a posterior-lateral approach, and also lateral, anterior-lateral, and anterior approaches. It is further contemplated that a single passage can be formed or more than two passages can be formed for any of these approaches.

In the illustrated embodiment, a second expandable device 130 and a second delivery instrument 150 are provided for placement through the second passage 62. Expandable device 130 and delivery instrument 150 can be identical to expandable device 30 and delivery instrument 50 discussed above, although such is not required. It is further contemplated that the same delivery instrument 50 can be employed to position the second expandable device 130 after placement and expansion of the first expandable device 30.

Unexpanded expandable devices 30, 130 are attached to respective ones of the collapsed distal portions 54, 154 of delivery instruments 50, 150 for delivery to the operative site. It is contemplated that the attachment can be provided by adhesive, frictional or form-fitting interengagement, or mechanical fasteners, for example. Expandable devices 30, 130 are then placed through the respective passages 60, 62 and into the intravertebral space of vertebra V1. A radio-contrast fluid, saline solution, compressed air, or other suitable fluid can be delivered to distal portions 54, 154 through shafts 52, 152 by a syringe or pump

operable. The fluid provides sufficient pressure for expansion of expandable elements 55, 155 and thus expand expandable devices 30, 130 as shown in Figs. 5 and 6. As the pressure and volume of the respective expandable elements 55, 155 increase, the first and second portions of expandable devices 30, 130 are gradually separated and provide an interface that compresses the surrounding cancellous bone to, for example, restore to height H4 a collapsed or fractured vertebra V1.

Expandable elements 55, 155 are then deflated or collapsed, and distal portions 54, 154 removed from their respective expanded expandable devices 30, 130 as shown in Figs. 7 and 8. Expandable devices 30, 130 can be adapted to maintain the desired vertebral height H4 after removal of expandable elements 55, 155 without internal pressure or support being applied to the vertebral body or the expanded devices 30, 130. The expanded devices 30, 130 provide a cavity for placement of bone filler material under low pressures and high viscosity, reducing the time for curing and stabilization to be supplemented with the bone filler material.

Bone filler material 64 is then placed in cavity 40 of the expanded expandable device 30, and can also be placed in cavity 140 of expandable device 130. Passages 60, 62 can also be filled with bone filler material 64. Bone filler material 64 can be deposited, packed, or injected into the cavities 40, 140 of expanded expandable devices 30, 130 and/or into the intravertebral space adjacent thereto to provide long term support and stability of vertebra V1 with bone formation.

Any suitable osteogenic material or composition is contemplated for the filler material, including autograft, allograft, xenograft, demineralized bone, and synthetic and natural bone graft substitutes, such as bioceramics and polymers, and osteoinductive factors. The terms osteogenic material or osteogenic composition used herein broadly include any material that promotes bone growth or healing including autograft, allograft, xenograft, bone graft substitutes and natural, synthetic and recombinant proteins, hormones and the like.

Autograft can be harvested from locations such as the iliac crest using drills, gouges, curettes, and trephines and other tools and methods which are well known to surgeons in this field. Preferably, autograft is harvested from the iliac crest with a

minimally invasive donor surgery. The osteogenic material may also include bone reamed away by the surgeon while preparing the endplates.

Natural and synthetic graft substitutes which replace the structure or function of bone are also contemplated for the osteogenic composition. Any such graft substitute is contemplated, including for example, demineralized bone matrix, demineralized bone matrix with bone chips, PMMA and other injectable synthetic bone cements, mineral compositions, and bioceramics. A vast array of bioceramic materials, including BIOGLASS®, hydroxyapatite, and calcium phosphate compositions known in the art which can be used to advantage for this purpose. Preferred calcium compositions include bioactive glasses, tricalcium phosphates, and hydroxyapatites. In one embodiment, the graft substitute is a biphasic calcium phosphate ceramic including tricalcium phosphate and hydroxyapatite.

In some embodiments, the osteogenic compositions used can comprise a therapeutically effective amount to stimulate or induce bone growth of a bone inductive or growth factor or protein in a pharmaceutically acceptable carrier. Osteoinductive factors that are recombinant human bone morphogenetic proteins (rhBMPs) are contemplated because they are readily available and do not contribute to the spread of infectious diseases. The bone morphogenetic protein can be a rhBMP-2, rhBMP-4 or heterodimers thereof. However, any bone morphogenetic protein is contemplated including bone morphogenetic proteins designated as BMP-1 through BPM-13.

The choice of carrier material for the osteogenic composition is based on biocompatibility, biodegradability, mechanical properties, and interface properties as well as the structure of the expandable device. Potential carriers include calcium sulphates, polylactic acids, polyanhydrides, collagen, calcium phosphates, polymeric acrylic esters, and demineralized bone. The carrier may be any suitable carrier capable of delivering the proteins. The carrier can be capable of being eventually resorbed into the body, such as an absorbable collagen sponge marketed by Integra LifeSciences Corporation under the trade name Helistat® Absorbable Collagen Hemostatic Agent. Another carrier is a biphasic calcium phosphate ceramic. Ceramic blocks are commercially available from Sofamor Danek Group, B.P. 4-62180 Rang-du-Fliers, France, and Bioland, 132 Rou d Espangne, 31100 Toulouse, France. The osteoinductive factor is introduced into the carrier in any

suitable manner. For example, the carrier may be soaked in a solution containing the factor. One preferred embodiment contemplates use of OSTEOFIL® allograph paste sold by Regeneration Technologies, Inc. The allograph paste can be supplemented with a local autograft obtained from the cutting operation.

Referring now to Figs. 9 through 14, there is shown an example of a surgical technique employing another embodiment expandable device and delivery instrument intravertebrally for repair and/or restoration of a collapsed or pressure fractured vertebral body. In Figs. 9 and 10, there is shown a spinal column segment including vertebra V1 having upper endplate E1 and lower endplate E2. Vertebra V1 includes a reduced anterior height configuration H3 as a result of a compression fracture, collapse or other deformity or condition of one or each of the endplates E1, E2 and the vertebral body extending therebetween.

In Figs. 9-14, expandable devices 230, 330 are provided that are similar to expandable device 30 discussed above, but include a tapered configuration such that the distal ends 232, 332 can expand or separate a greater distance than proximal ends 234, 334. Accordingly, when positioned in the vertebral body V1 from a posterior approach, distal ends 232, 332 are positionable adjacent the anterior portion of vertebra V1 requiring restoration. Other tapered configurations are also contemplated such as, for example, proximal ends that can expand or separate a greater distance than the distal ends. Such an alternate device could be employed in a vertebra with an anterior fracture in an anterior approach to the vertebra.

Delivery instruments 250, 350 can be configured like delivery instrument 50 discussed above, but include one or more expandable elements 255, 355 along distal portions 254, 354 that include a shape adapted to expand the internal cavities 236, 336 of expandable devices 230, 330. Expandable elements 255, 355 can be tapered, stepped or otherwise configured to effect greater expansion at distal ends 232, 332 than at proximal ends 234, 334.

Unexpanded expandable devices 230, 330 are attached to collapsed expandable elements 254, 354 of delivery instruments 250, 350 for delivery of expandable devices 230, 330 to the operative site. Expandable devices 230, 330 are then placed through the passages 60, 62 and into the intravertebral space of vertebra V1. A radio-contrast fluid, saline solution, compressed air, or other suitable fluid can be delivered through shafts 252, 352 to expandable elements 255, 355 through a syringe or pump operable to provide sufficient pressure to expand expandable devices 230, 330 as shown in Figs. 11 and 12. As the pressure

and volume of the respective expandable elements 255, 355 increase, expandable devices 230, 330 are gradually expanded and compress the surrounding cancellous bone to restore the collapsed vertebra V1 from height H3 to a desired vertebral body height H4 between endplates E1 and E2.

Expandable elements 255, 355 are then deflated or collapsed and removed from their respective expanded expandable devices 230, 330, as shown in Figs. 13 and 14. Bone filler material 64 can be deposited, packed, or injected into the cavities 236, 336 of the expanded devices 230, 330 to provide long term support and stability of vertebra V1 during bone formation.

Intravertebral reduction can also be conducted from other approaches to the vertebral body, such as a lateral approach shown in Figs. 15-20. A lateral access passage 68 is formed in vertebra V1 to provide assess to the cancellous bony material in the interior of the vertebral body. Expandable device 30 is positioned on distal portion 54 of delivery instrument 50, and delivery instrument 50 is positioned to deliver expandable device 50 into vertebra V1 through lateral access passage 68, as shown in Figs. 15 and 16. Expandable element 55 is expanded to expand expandable device 30 in vertebra V1, as shown in Figs. 17 and 18. The expanded expandable device 30 compresses the cancellous bony tissue and restored vertebra V1 to a restored height H4 adjacent at the anterior portion of vertebra V1. In Figs. 19 and 20, delivery instrument 50 is removed from access passage 68, and bone filler 64 is positioned in the cavity of expandable device 30.

In the embodiment of Figs 15-20, it is also contemplated that expandable device 30 can be configured to separate a greater distance along the side thereof positioned adjacent the vertebral fracture.

The expandable devices contemplated herein can be provided in various forms. For example, as shown in Fig. 21, the first and second portions of the expandable device could be adjustably connected along overlapping sidewalls of the first and second portions. Expandable device 430 includes a first portion 432 and a second portion 442 similar to expandable device 30 discussed above. First portion 432 includes opposite sidewalls 434, 435, and second portion 442 includes opposite sidewalls 444, 445. First portion 432 and second portion 442 define a cavity 438 therebetween into which expandable element 55 of delivery instrument 50 can be positioned.

The adjacent sidewalls 434, 444 include a number of interdigitating teeth that engage one another, and the adjacent sidewalls 435, 445 include a number of interdigitating teeth that engage one another. The interdigitating teeth allow first and second portions 432, 442 to be uni-directionally moved away from one another upon expansion of expandable element 55 in cavity 438 as indicated by arrows 440. The interdigitating teeth can include a ratcheted configuration that resists or prevents movement of first and second portions 432, 442 toward one another after expansion. Expandable device 430 maintains support of the reduced vertebra immediately after reduction, even after removal of expandable element 55 from cavity 438. The interdigitating teeth further define a number of expanded or separated positions between first and second portions 432, 442 that provide various reduction heights that can be effected with a single expandable device 430.

In another example, the expandable devices could be made from a shape memory material or ductile that is unexpanded or collapsed for positioning on the delivery instrument prior to insertion. Upon insertion to the surgical location, the device is radially expandable with inflation or enlargement of the delivery instrument to assume an expanded configuration. Expansion of the expandable device can be accomplished with temperature changes, chemical changes, or force induced changes with inflation or enlargement of the enlargeable member 55 of delivery instrument 50.

For example, in Fig. 22 there is shown expandable device 530 including a body 538 defining an interior cavity 532 extending between a proximal end 534 and a distal end 536. Body 538 includes a number of portions 542 therearound that each define an elongated flex opening 544. Segments 542 are interconnected by hinges 546. Body 538 is made of sufficiently ductile or formable material such that upon exertion of a radial expansion force, indicated by arrows 540, flex openings 544 can enlarge and hinges 546 can stretch to allow segments 542 to move away from one another, enlarging interior cavity 532.

In a further example, the expandable devices can include a first mechanical configuration that allows a collapsed condition for insertion of the device with the delivery instrument. After insertion, the device can be mechanically adjusted upon inflation or enlargement of the distal portion of the delivery instrument to assume an expanded condition at the operative site. Examples of such expandable devices include those made from a wire

mesh material, and devices with first and second portion connected by mechanical linkages, as shown in Figs. 23-25.

In Figs. 23-25 device 630 includes a first portion 632 and a second portion 642. Linkages 650 movably couple first and second portions 632, 642 to one another. Linkages 650 include first and second members 652, 654 pivotally coupled to one another. Members 652, 654 each include a first end positioned in respective ones of the receptacles 634 of first portion 632, and opposite second ends positioned in respective ones of the receptacles 644 of second portion 642. The ends of the members 650, 652 can include a configuration that interdigitates with a ratchet surface formed along the respective receptacles 634, 644. In the unexpanded configuration shown in Fig. 23, the ends of members 652, 654 are positioned at the outer ends of the respective receptacles 634, 644.

As first and second portions 632, 642 are uni-directionally moved away from one another with expandable element 55 in cavity 638, as indicated by arrows 640, the ends of members 650, 652 move longitudinally toward one another along the receptacles 634, 644 of each of the respective first and second portions 632, 642, as shown in Fig. 24. The rigid members 652, 654 move first and second portions 632, 642 away from one another, and engage the ratchet surfaces along receptacles 634, 644 to maintain the expanded or separated position between first and second portions 632, 642, as shown in Figs. 24 and 25.

Figs. 26A and 26B are a plan view and an elevation view in partial section, respectively, of another embodiment pair of collapsed expandable devices 680 and associated delivery instruments 690 positioned in an intravertebral space of vertebra V1. The collapsed or unexpanded expandable devices 680 are secured around the respective unexpanded expandable element 694 at a distal end of delivery instrument 690 for delivery to the intravertebral space. In the illustrated embodiment, vertebra V1 is accessed from a posterior approach through the pedicles, although other approaches are also contemplated. Expandable devices 680 each include a width between opposite sides 686, 688.

Figs. 27A and 27B are a plan view and an elevation view in partial section, respectively, with expandable devices 680 expanded with a fluid delivered through shafts 692 of delivery instruments 690. In the expanded condition, lower and upper surfaces 682, 684 of expandable device 680 compress the surrounding cancellous bone to reduce vertebra V1 from height H3 to a greater restored height H4. The widths between opposite sides 686, 688 of

expandable devices 680 remain substantially constant during and after expansion. Accordingly, expandable devices 680 are vertically expandable to increase their height while their widths remain constant, such as shown with expandable devices 430 and 630 discussed above.

Figs. 28A and 28B are a plan view and an elevation view in partial section, respectively, with the expanded expandable devices 680 in the restored vertebra V1 of the spinal column segment and the delivery instruments 690 removed from cavities 685 of expandable devices 680. Filler material for bone growth can be placed in cavities 685 and in approaches 60, 62 as discussed above.

Figs. 29A and 29B are a plan view and an elevation view in partial section, respectively, of another embodiment pair of collapsed expandable devices 700 and associated delivery instruments 710 positioned in vertebra V1. The collapsed or unexpanded expandable devices 700 are secured around the respective unexpanded expandable element 714 at a distal end of delivery instrument 710 for delivery to the intravertebral space. In the illustrated embodiment, the intravertebral space is accessed from a posterior approach through the pedicles, although other approaches are also contemplated. Expandable devices 700 include a width between opposite sides 703, 705.

Figs. 30A and 30B are a plan view and an elevation view in partial section, respectively, with expandable devices 700 expanded with a fluid delivered through shafts 712 of delivery instruments 710. In the expanded condition, lower and upper surfaces 702, 704 of expandable devices 700 compress the surrounding cancellous bone and separate the opposite vertebral endplates to reduce vertebra V1 from height H3 to provide a restored height H4. The widths between opposite sides 703, 705 of expandable devices 700 remain substantially constant during and after expansion. Accordingly, expandable devices 700 are vertically expandable to increase their height while their widths remain constant.

Expandable devices 700 are tapered along the length thereof between an anterior end and a posterior end. In the illustrated embodiment, the posterior end includes a first height 708, and the anterior end includes a second height 709 which is greater than first height 708. This tapered height provides a greater reduction of vertebra V1 adjacent the anterior portion thereof, which can be targeted to the region of greatest compression such as provided with an anterior vertebral fracture.

Figs. 31A and 31B are a plan view and an elevation view in partial section, respectively, with the expanded expandable devices 700 in the reduced vertebra V1 of the spinal column segment and the delivery instruments 710 removed from cavities 706 of expandable devices 700. Filler material for bone growth can be placed in cavities 706 and in approaches 60, 62 as discussed above.

Figs. 32A and 32B are a plan view and an elevation view in partial section, respectively, of another embodiment pair of collapsed expandable devices 720 and associated delivery instruments 730 positioned in an intravertebral space of vertebra V1. The collapsed or unexpanded expandable devices 720 are secured around the unexpanded expandable elements 734, 736 at a distal end of delivery instrument 730 for delivery to the intravertebral space. Expandable devices 720 each include a posterior portion 723 and an anterior portion 725, and a width between opposite sides 727, 729. The height and width of expandable devices 720 are substantially uniform in their collapsed or unexpanded condition along portions 723, 725.

Figs. 33A and 33B are a plan view and an elevation view in partial section, respectively, with expandable devices 720 expanded with a fluid delivered through shafts 732 of delivery instruments 730. In the expanded condition, posterior and anterior portions 723, 725 of expandable devices 720 compress cancellous bone and separate the opposite vertebral endplates E1, E2 to reduce vertebra V1 from compressed height H3 to provide a restored vertebral height H4. The width between opposite sides 727, 729 of expandable devices 720 remains substantially constant during and after expansion. Accordingly, expandable devices 720 are vertically expandable while their widths remain constant.

Expandable devices 720 are stepped in height between anterior portion 725 and posterior portion 723 to provide a greater anterior height for the expanded expandable devices 720. This stepped height provides a targeted reduction of vertebra V1 anteriorly where, for anterior fractures, the vertebral compression is greatest. To facilitate this stepped and targeted reduction, delivery instrument 730 can be provided with an anterior expandable element 734 and a posterior expandable element 736. Expandable elements 734, 736 can be provided with differing heights in their expanded configurations that conform to the expanded height of respective ones of the anterior and posterior portions 725, 723 in which expandable elements 734, 736 are positioned.

Figs. 34A and 34B are a plan view and an elevation view in partial section, respectively, with the expanded expandable devices 720 in the reduced vertebra V1 of the spinal column segment and the delivery instruments 730 removed from cavities 726 of expandable devices 720. Filler material for bone growth can be placed in cavities 726 and in approaches 60, 62 as discussed above.

Figs. 35A and 35B are a plan view and an elevation view in partial section, respectively, of another embodiment collapsed expandable device 740 and associated delivery instrument 750 positioned in a reduced height vertebra V1. The collapsed or unexpanded expandable device 740 is secured around the unexpanded expandable element 754 at a distal end of delivery instrument 750 for delivery to the reduced height vertebra V1. Expandable device 740 includes, in the collapsed condition, a convexly curved anterior wall 742 and a concavely curved posterior wall 744. Walls 742, 744 form a banana or kidney shape that facilitates placement of expandable device 740 in the intravertebral space for bi-lateral support of endplates E1, E2 of vertebra V1 from a single uni-lateral approach 60. Accordingly, the invasiveness of the procedure is even further reduced.

Figs. 36A and 36B are a plan view and an elevation view in partial section, respectively, with expandable device 740 expanded with a fluid delivered through shaft 752 of delivery instrument 750. In the expanded condition, upper and lower portions 747, 748 of expandable device 740 compress the surrounding cancellous bone and separate the opposite vertebral endplates E1, E2 to reduce vertebra V1 to a restored height H4. Expansion of expandable device 740 can result in posterior wall 744 moving posteriorly such that in the expanded condition, posterior wall 744 is substantially linear to provide expandable device 740 with a D shape.

Expandable device 740 includes convexly curved anterior wall 742 which facilitates placement of expandable device 740 along a curved insertion path from approach 60 in which the anterior wall 742 conforms to the profile of the curved anterior portion of vertebra V1. In the illustrated embodiment, expandable device 740 is positioned in the anterior half of vertebra V1. Expandable element 754 can be provided with a shape that conforms to the D-shaped interior cavity 746 when expanded.

Figs. 37A and 37B are a plan view and an elevation view in partial section, respectively, with the expanded expandable device 740 in the restored vertebra V1 of the

spinal column segment and the delivery instrument 750 removed from cavity 746 of expandable device 740. Filler material for bone growth can be placed in cavity 746 and in approach 60 as discussed above.

Figs. 38A and 38B are a plan view and an elevation view in partial section, respectively, of another embodiment collapsed expandable device 760 and associated delivery instrument 770 positioned in a reduced height vertebra V1. The collapsed or unexpanded expandable device 760 is secured around the unexpanded expandable element 774 at a distal end of delivery instrument 770 for delivery to the intravertebral space from lateral approach 68. Expandable device 760 includes a first portion 762 and a second portion 764 engaged along opposite sides of expandable element 774 and positionable toward respective ones of the endplates E1 and E2.

Figs. 39A and 39B are a plan view and an elevation view in partial section, respectively, with expandable device 760 expanded by manipulating shaft 772 of delivery instrument 770 to expand expandable element 774. In the expanded condition, first and second portions 762, 764 of expandable device 760 compress the adjacent cancellous bone and separate opposite vertebral endplates E1, E2 to reduce vertebra V1 and provide a restored height H4.

Figs. 40A and 40B are a plan view and an elevation view in partial section, respectively, with the expanded expandable device 760 in the restored vertebra V1 of the spinal column segment and the delivery instrument 770 removed from cavity 766 of expandable device 760. Filler material for bone growth can be placed in cavity 766 and in approach 68 as discussed above.

Further details of delivery instrument 770 are provided in Figs. 41A and 41B. Shaft 772 includes a proximal handle portion 773 and a distal portion 776 extending through expandable element 774. Expandable element 774 includes a first pivoting linkage 778 and a second pivoting linkage 780. Linkages 778, 780 each include an intermediate pivot point engaged to and movable with distal portion 776. Linkages 778, 780 further include reduction members 782, 784 coupled at the upper and lower ends thereof.

Distal portion 776 is coupled to linkages 778, 780 so that, as shaft 772 is rotated about its axis with handle portion 773 as indicated in Fig. 41A, the pivoting intermediate portions of linkages 778, 780 are drawn toward one another to move reduction members 782, 784

away from one another, as shown in Fig. 41B. When positioned in a cavity of an expandable device, reduction members 782, 784 contact adjacent portions of the expandable device to expand the expandable device and reduce the vertebra. When the desired reduction has been achieved, expandable device 770 can be removed from the expandable device by rotating shaft 772 in the opposite direction and move reduction members 782, 784 toward one another.

The expandable devices herein can be provided with one or more openings, windows or other structure that allows communication between the interior cavity thereof and the adjacent bony tissue to facilitate bone ingrowth. The expandable devices can include a single cavity or multiple cavities. It is further contemplated that the expandable devices could be provided with support mechanisms positionable in the cavity to maintain or assist in maintaining an expanded condition of the device.

The expandable devices discussed herein can be made from any bio-compatible material, including metals, polymers and composites. Examples of metals include titanium and titanium alloys; nickel titanium alloys; stainless steel; and cobalt chrome alloys. Examples of polymers include polyaryletherketone; polyetheretherketone; polysulfone; polyolefin; polyethylene; tyrosine-based polycarbonate; polyester; polylactide; polyglicolide; polyorthoester; polyphosphazene; polyhydroxylbutyrate; and polyhydroxylvalerate, for example. Examples of composites include carbon filled composites; hydroxy-apetite filled composites; bioactive glass filled composites; and cortical bone chip filled composites, for example.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character. All changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. A method for intravertebral reduction, comprising:

accessing a vertebral body;

forming an access passage into the vertebral body;

delivering an expandable device through the passage into the vertebral body in an unexpanded condition;

expanding the expandable device in the vertebral body with an expandable element;

removing the expandable element; and

placing bone filler material within the expanded expandable device.

2. The method of claim 1, wherein accessing the vertebral body includes accessing the vertebral body through at least one pedicle of the vertebra.

3. The method of claim 1, wherein accessing the vertebral body includes accessing the vertebral body from a lateral approach.

4. The method of claim 1, wherein forming the access passage includes forming the access passage into the vertebral body from a location anterior of posterior vertebral elements of the vertebral body.

5. The method of claim 1, wherein forming the access passage includes drilling a hole into the cancellous bony tissue of the vertebral body.

6. The method of claim 1, further comprising mounting the expandable device on a distal portion of a delivery instrument.

7. The method of claim 6, wherein the distal portion includes the expandable member, and mounting the expandable device includes mounting the expandable device on the expandable element before delivering the expandable device through the passage.

8. The method of claim 1, wherein expanding the expandable device includes inflating the expandable element.

9. The method of claim 8, further comprising deflating the expandable element before removing the expandable element.

10. The method of claim 1, wherein expanding the expandable device includes moving a first portion and a second portion of the expandable device away from one another.

11. The method of claim 10, wherein the first portion and second portion are substantially rigid.

12. The method of claim 11, wherein the first portion and the second portion include bone engaging features along outer surfaces thereof.

13. The method of claim 10, wherein first portion and second portion extend between a proximal end and a distal end of the expandable device, and when expanded the first portion and second portion provide a first height adjacent the distal end and a second height adjacent the proximal end, one of the first and second heights being greater than the other of the first and second heights.

14. The method of claim 13, further comprising orienting the greater height anteriorly in the vertebral body.

15. The method of claim 13, wherein the first and second portions are tapered between the first and second heights.

16. The method of claim 13, wherein the first and second portions include a stepped configuration between the first and second heights.

17. The method of claim 10, wherein the first portion and the second portion define a cavity therebetween, and placing bone filler material includes placing bone filler material in the cavity.

18. The method of claim 1, wherein the vertebral body includes an anterior portion having a collapsed height between opposite endplates thereof, and expanding the expandable device moves at least one of the opposite endplates away from the other to provide the anterior portion of the vertebral body with a restored height between the opposite endplates, the restored height being greater than the collapsed height.

19. A method for intravertebral reduction, comprising:

accessing a vertebral body;

forming an access passage into the vertebral body;

delivering an expandable device through the passage into the vertebral body in an unexpanded condition;

expanding the expandable device with an expandable element in the expandable device to restore a vertebral body height;

removing the expandable element; and

maintaining the restored vertebral height device with the expanded expandable device.

20. The method of claim 19, further comprising placing bone filler material in the expanded expandable device.

21. The method of claim 19, wherein expanding the expandable device includes positioning the expanding element in a cavity of the expandable device and expanding the expandable element in the cavity.

22. The method of claim 21, wherein the expandable element comprises a distal portion of an instrument to deliver the expandable device.

23. The method of claim 22, wherein the expandable element includes an interior inflatable with fluid.

24. The method of claim 19, wherein expanding the expandable device includes expanding the expandable device uni-directionally.

25. The method of claim 19, wherein expanding the expandable device includes expanding the expandable device radially.

26. The method of claim 19, wherein accessing the vertebral body includes accessing the vertebral body through at least one pedicle of the vertebra.

27. The method of claim 19, wherein accessing the vertebral body includes accessing the vertebral body from a lateral approach.

28. The method of claim 19, wherein expanding the expandable device includes moving a first portion and a second portion of the expandable device away from one another.

29. The method of claim 28, wherein the first portion and second portion are substantially rigid.

30. The method of claim 28, wherein first portion and second portion each extend between a proximal end and a distal end of the expandable device, and when expanded the first portion and second portion are separated by a first height adjacent the distal end and a second height adjacent the proximal end, one of the first and second heights being greater than the other of the first and second heights.

31. The method of claim 30, further comprising orienting the end with the greater height anteriorly in the vertebra.

32. The method of claim 19, wherein the vertebral body includes an anterior portion having a collapsed height between opposite endplates thereof, and expanding the expandable device moves at least one of the opposite endplates away from the other to provide the anterior portion of the vertebral body with a restored height between the opposite endplates, the restored height being greater than the collapsed height.

33. The method of claim 19, wherein forming the access passage includes forming the access passage through a pedicle of the vertebral body.

34. The method of claim 33, wherein in the unexpanded condition the expandable device includes a banana shape, and delivering the expandable device includes positioning the expandable device through the access passage and orienting a convexly curved anterior wall of the expandable device anteriorly in the vertebra.

35. The method of claim 33, further comprising:

forming a second access passage into the vertebral body through a second pedicle;

delivering a second expandable device through the passage into the vertebral body in an unexpanded condition and adjacent the expandable device; and

expanding the second expandable device with an expandable element in the expandable device to restore a vertebral body height.

36. The method of claim 19, wherein the expandable device includes a width which remains substantially constant in the unexpanded and expanded conditions.

37. A system for intravertebral reduction, comprising:

a delivery instrument including an expandable element along a distal portion thereof; and

an expandable device including a cavity, the expandable device being removably mountable to the expandable element with the expandable element in the cavity and each of the expandable device and the expandable element in an unexpanded condition, wherein the expandable device is deliverable to an intravertebral space in the unexpanded condition and

thereafter expandable with expansion of the expandable element to compress cancellous bone in the intravertebral space.

38. The system of claim 37, wherein the expandable element includes a balloon structure with an interior for receiving an expansion fluid.

39. The system of claim 38, wherein the expansion fluid is selectable from the group consisting of: saline solution, compressed air, and radio-contrast fluid.

40. The system of claim 38, wherein the delivery instrument includes a shaft defining a lumen in fluid communication with the interior of the expandable element.

41. The system of claim 37, wherein the expandable device includes a first portion and a second portion extending therealong, the first and second portions being movable away from one another upon expansion of the expandable element.

42. The system of claim 41, wherein the first and second portions each define an outer surface with bone engagement members therealong.

43. The system of claim 41, wherein the first and second portions are uni-directionally movable away from one another upon expansion of the expandable element.

44. The system of claim 41, wherein in an expanded configuration the first and second portions include outer surfaces adjacent distal ends thereof separated by a first height and outer surfaces adjacent proximal ends thereof separated by a second height, one of the first and second heights being greater than the other of the first and second heights.

45. The system of claim 44, wherein the expandable device is tapered between the first and second heights.

46. The system of claim 44, wherein the expandable device includes a stepped configuration between the first and second heights.

47. The system of claim 41, wherein the first and second portions include bone growth openings therethrough.

48. The system of claim 41, wherein the first and second portions are substantially rigid and the expandable element is non-rigid.

49. The system of claim 41, wherein the first and second portions are structured to maintain an expanded configuration after removal of the expandable element from the cavity therebetween.

50. The system of claim 41, further comprising bone filler material positionable in the cavity between the first and second portions.

51. The system of claim 50, wherein the bone filler material includes bone growth promoting material.

52. The system of claim 37, wherein the cavity opens at a distal and at a proximal end of the expandable device.

53. The system of claim 37, wherein in the unexpanded condition the expandable device includes a banana shape with a convexly curved anterior wall and a concavely curved posterior wall.

54. The system of claim 53, wherein when expanded the expandable device includes a D shape with the anterior wall convexly curved and the posterior wall linear.

55. A system for intravertebral reduction, comprising:

a delivery instrument including a non-rigid expandable element along a distal portion thereof; and

an expandable device including a cavity between substantially rigid first and second portions, the expandable device being structure for positioning in an intravertebral space, wherein the expandable element is expandable in the cavity to move the first and second portions away from one another and compress cancellous bone in the intravertebral space.

56. The system of claim 55, wherein the first and second portions each define an outer surface with bone engagement members therealong.

57. The system of claim 55, wherein the first and second portions remain movably engaged with one another during expansion of the expandable element.

58. The system of claim 55, wherein in an expanded configuration the first and second portions include outer surfaces adjacent distal ends thereof separated by a first height and outer surfaces adjacent proximal ends thereof separated by a second height, one of the first and second heights being greater than the other of the first and second heights.

59. The system of claim 58, wherein the expandable device is tapered between the first and second heights.

60. The system of claim 58, wherein the expandable device includes a stepped configuration between the first and second heights.

61. The system of claim 55, wherein the first and second portions include bone growth openings therethrough.

62. The system of claim 55, wherein the first and second portions are structured to maintain an expanded configuration after removal of the expandable element from the cavity therebetween.

63. The system of claim 55, further comprising bone filler material positionable in the cavity between the first and second portions.

64. The system of claim 55, wherein the expandable device is radially expandable.

65. The system of claim 55, wherein the expandable device includes a width between opposite sides thereof, the width remaining substantially constant in the unexpanded and expanded conditions.

66. The system of claim 65, wherein in the unexpanded condition the expandable device includes a banana shape with a convexly curved anterior wall and a concavely curved posterior wall.

67. The system of claim 66, wherein when expanded the expandable device includes a D shape with the anterior wall convexly curved and the posterior wall linear.

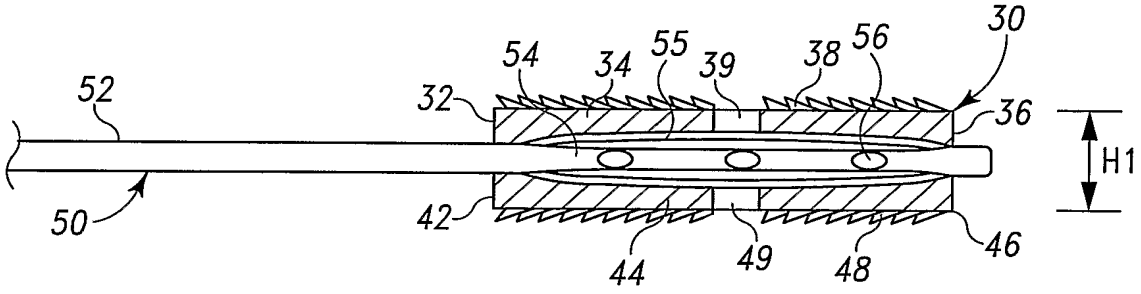
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Fig. 1

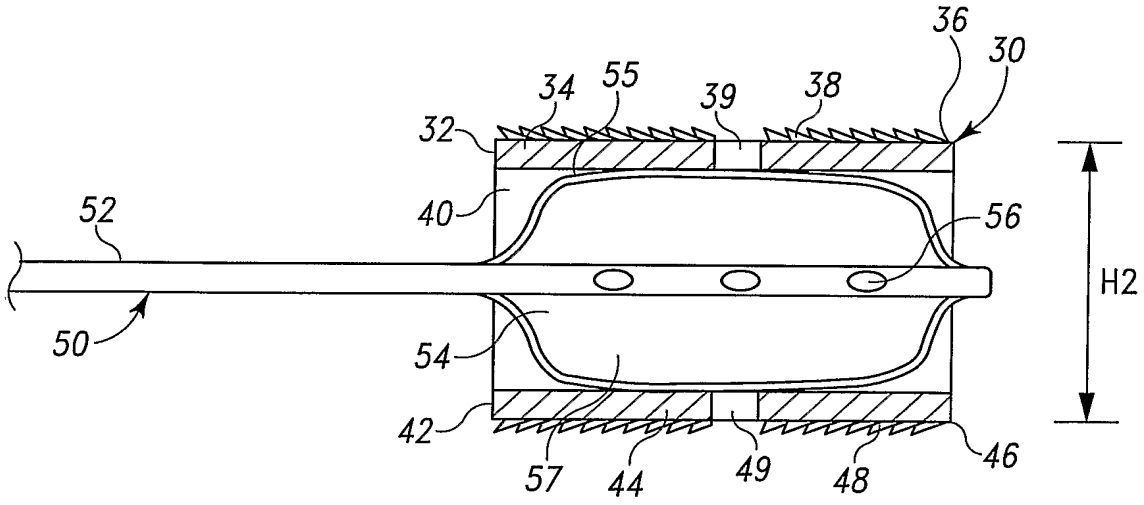
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Fig. 2

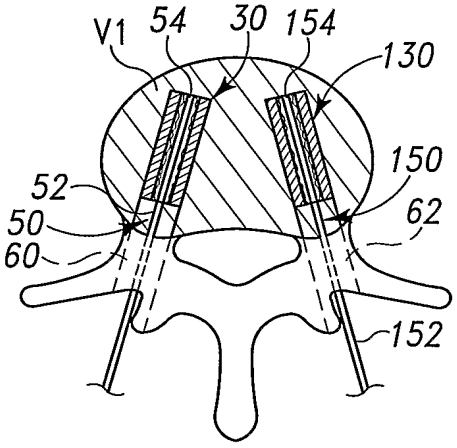

Fig. 3

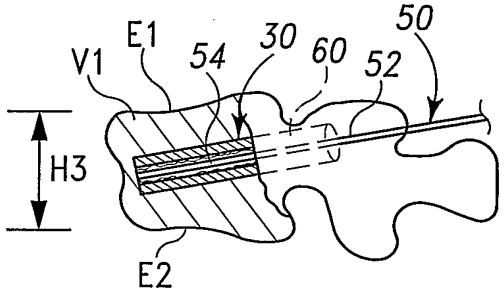

Fig. 4

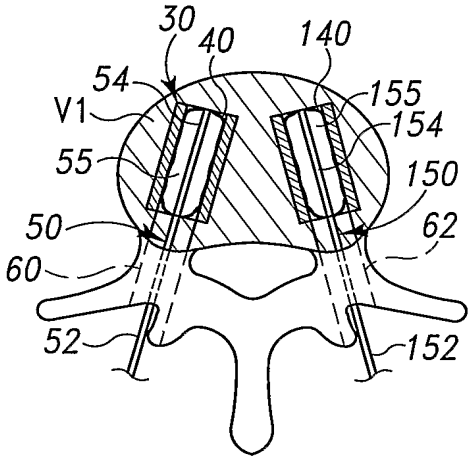

Fig. 5

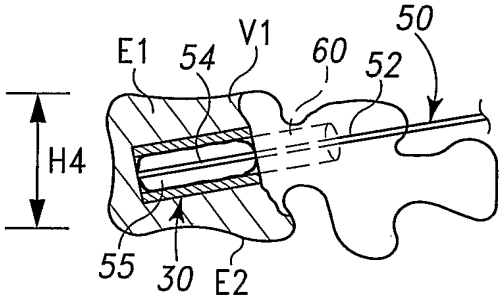

Fig. 6

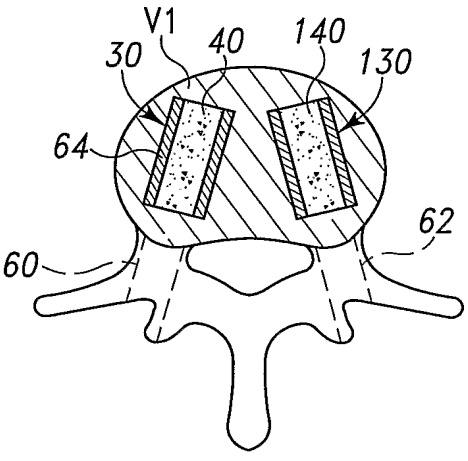

Fig. 7

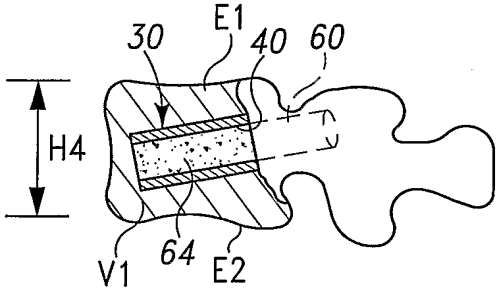

Fig. 8

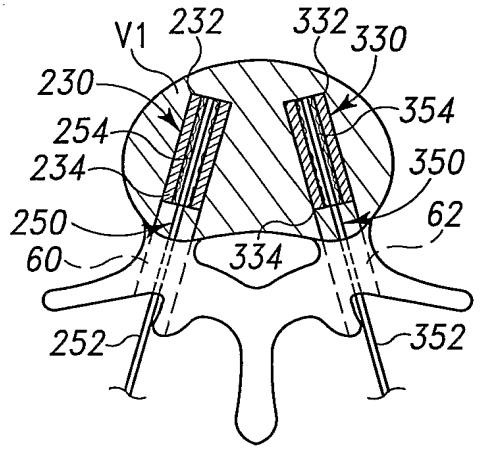

Fig. 9

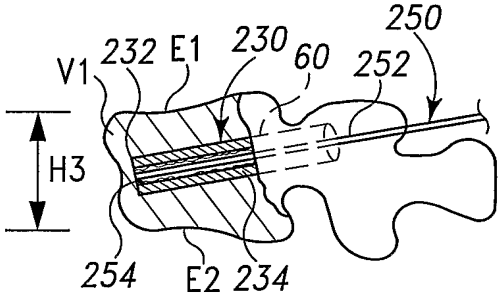

Fig. 10

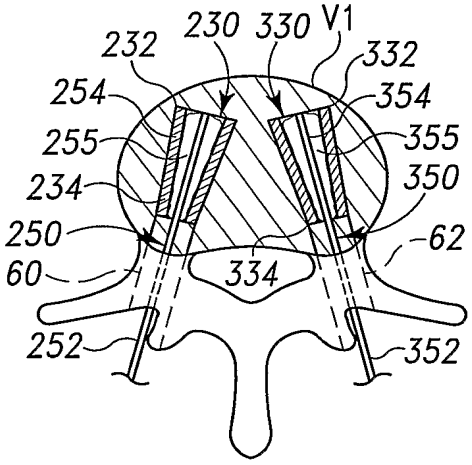

Fig. 11

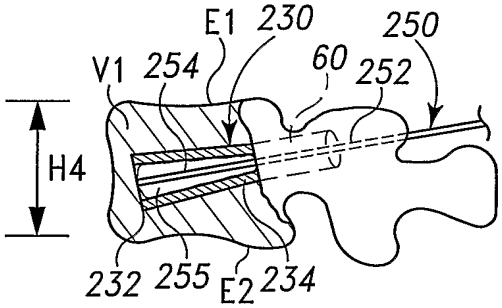

Fig. 12

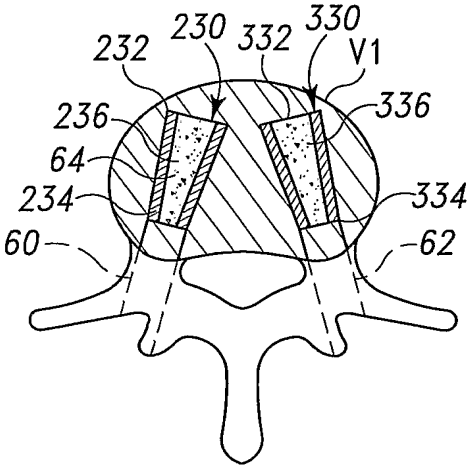

Fig. 13

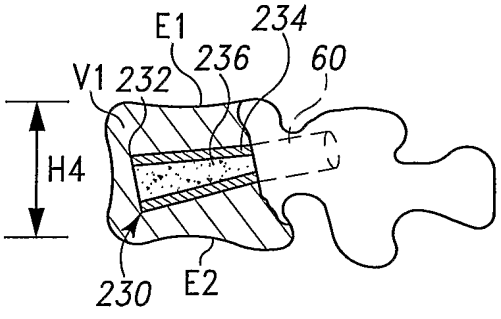

Fig. 14

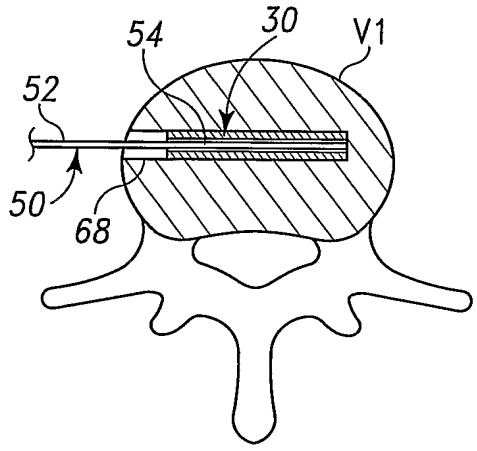

Fig. 15

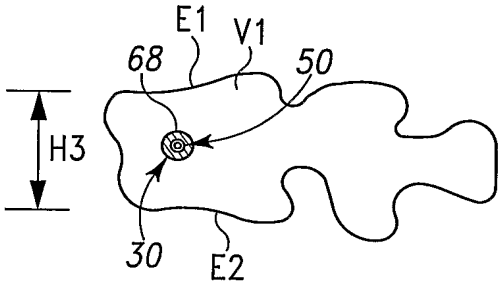

Fig. 16

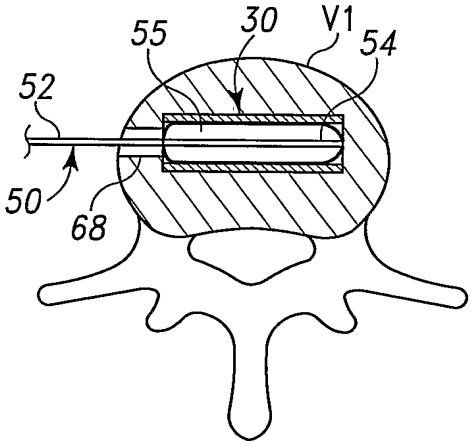

Fig. 17

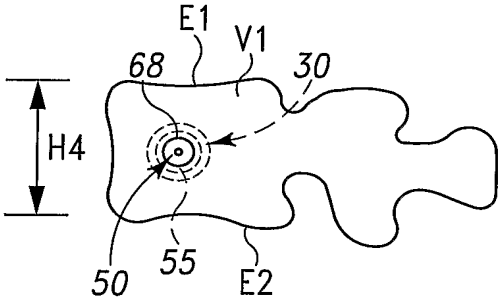

Fig. 18

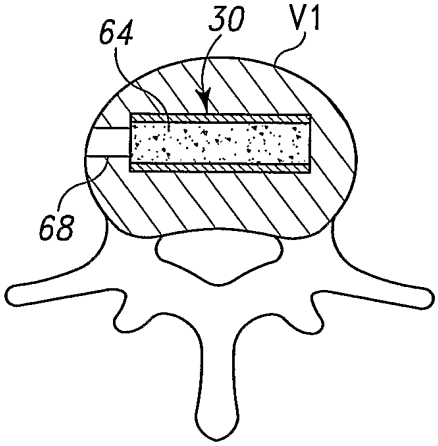

Fig. 19

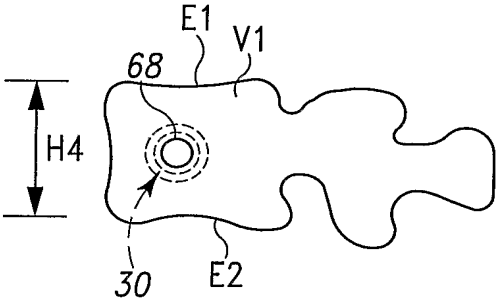

Fig. 20

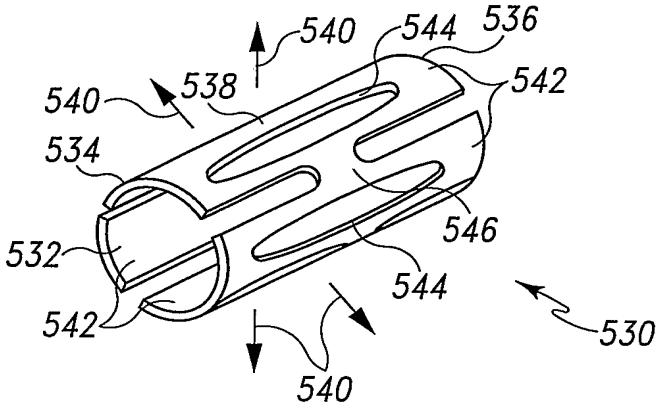

Fig. 22

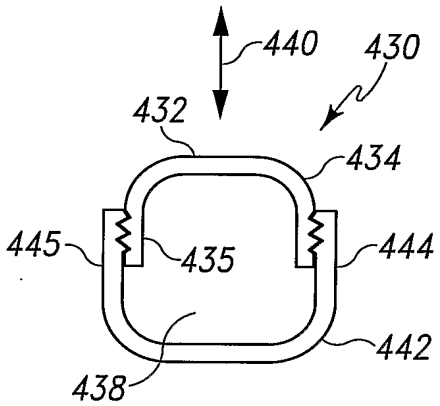

Fig. 21

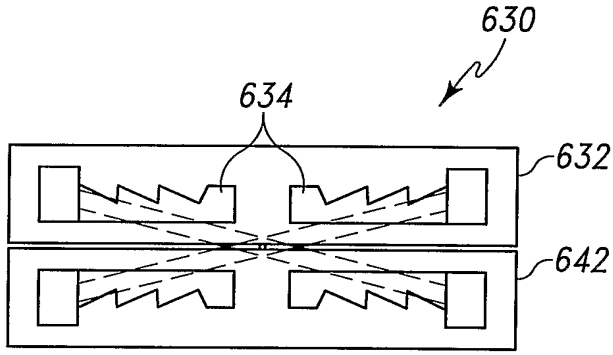

Fig. 23

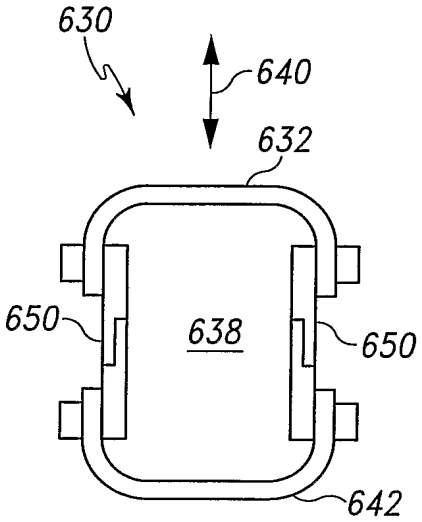

Fig. 25

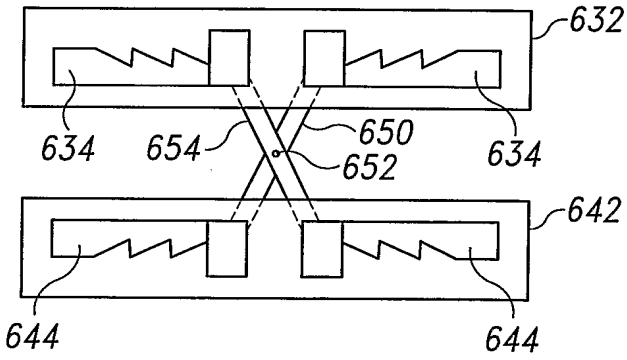

Fig. 24

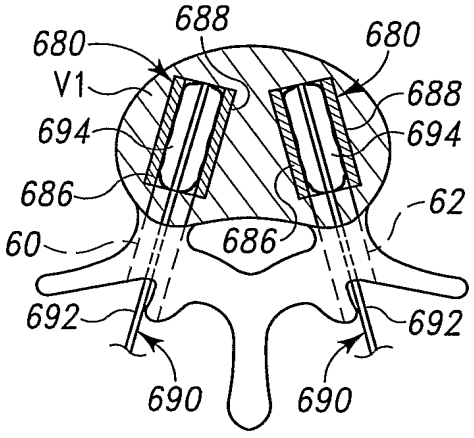

Fig. 26A

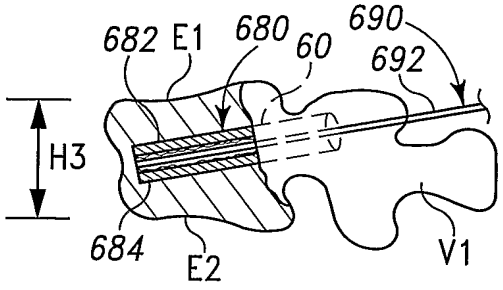

Fig. 26B

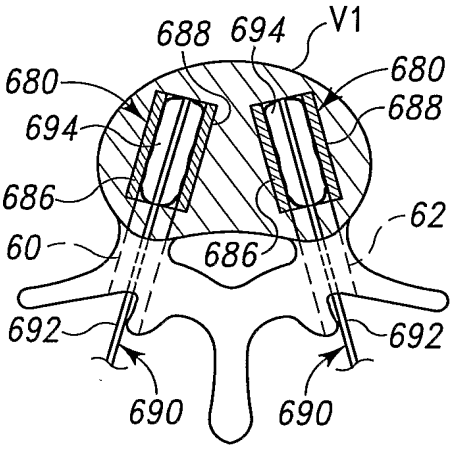

Fig. 27A

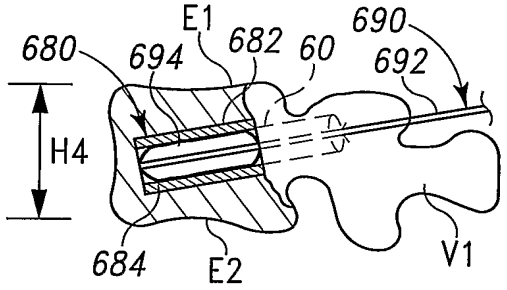

Fig. 27B

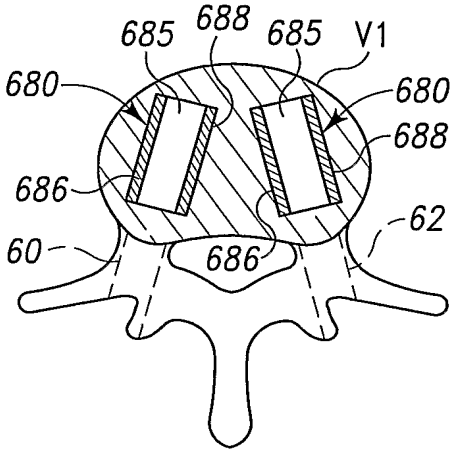

Fig. 28A

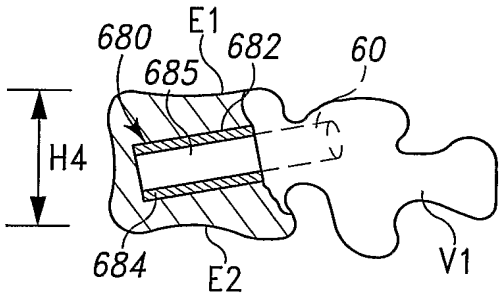

Fig. 28B

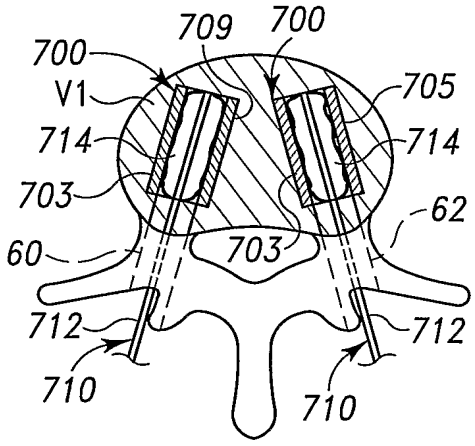

Fig. 29A

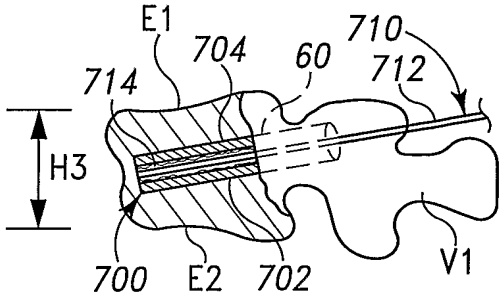

Fig. 29B

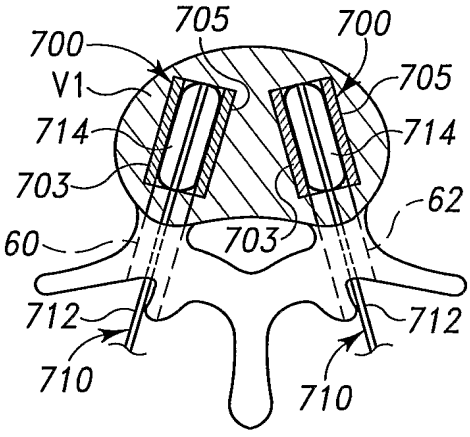

Fig. 30A

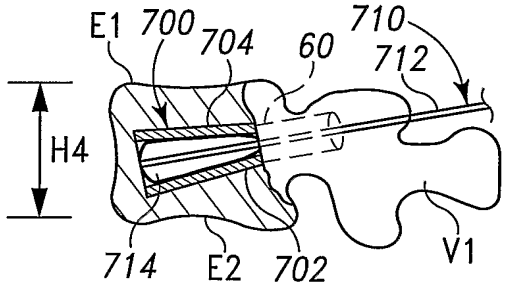

Fig. 30B

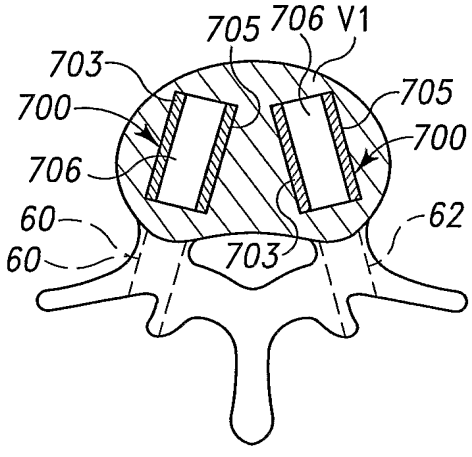

Fig. 31A

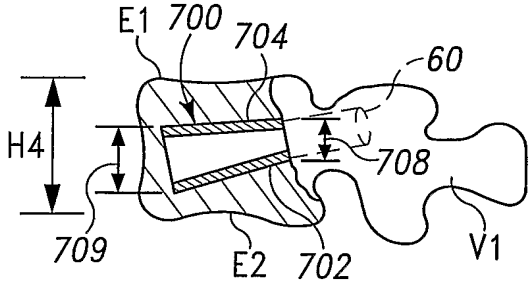

Fig. 31B

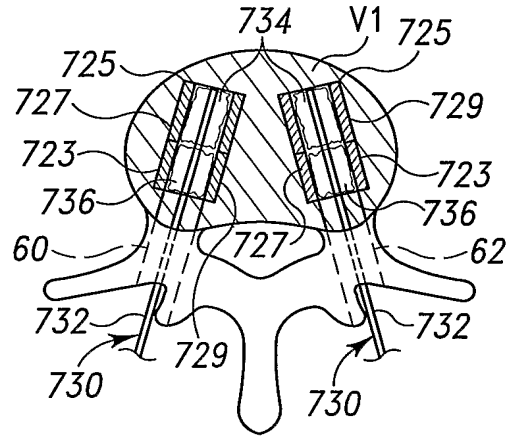

Fig. 32A

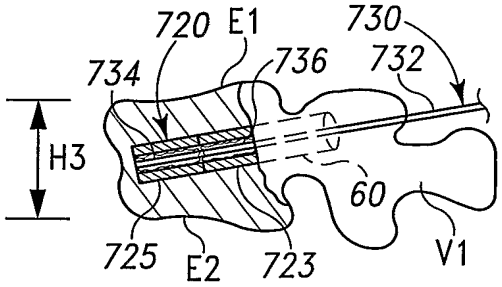

Fig. 32B

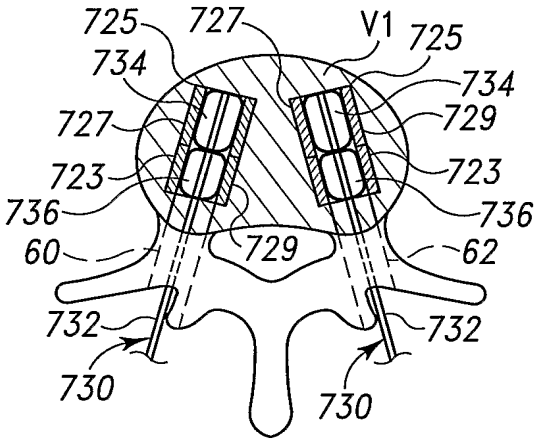

Fig. 33A

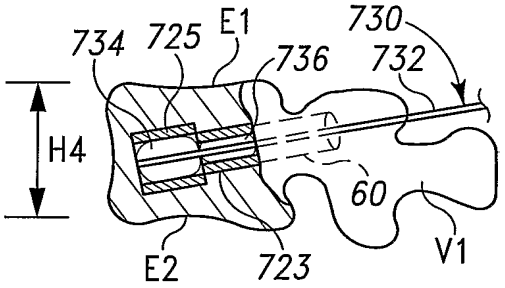

Fig. 33B

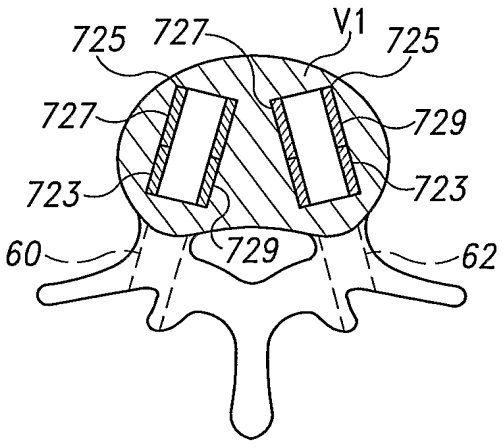

Fig. 34A

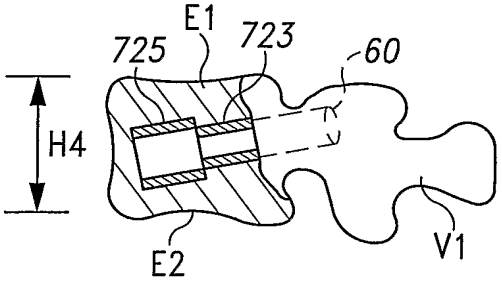

Fig. 34B

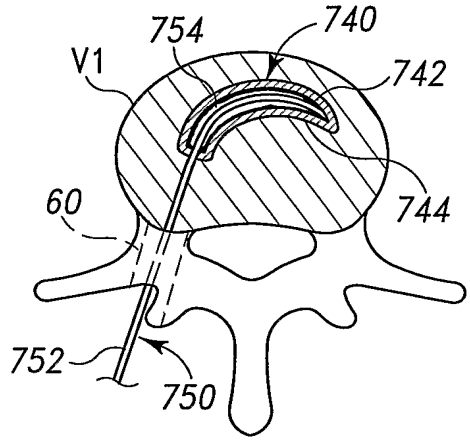

Fig. 35A

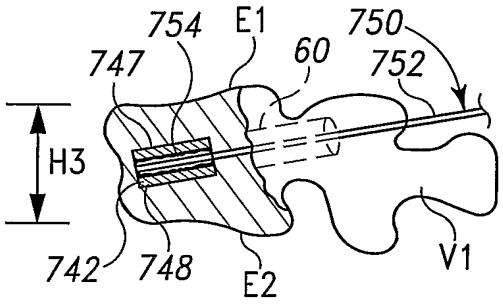

Fig. 35B

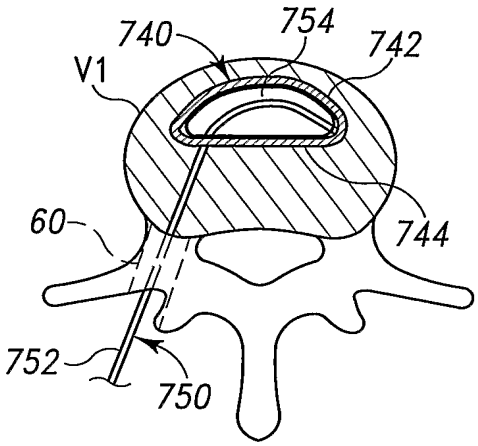

Fig. 36A

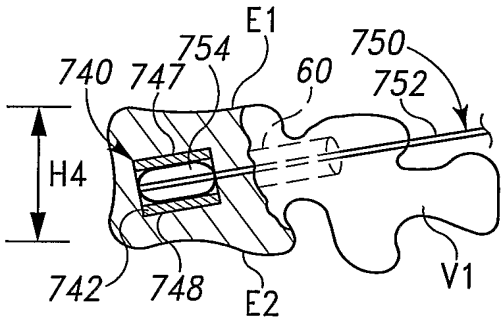

Fig. 36B

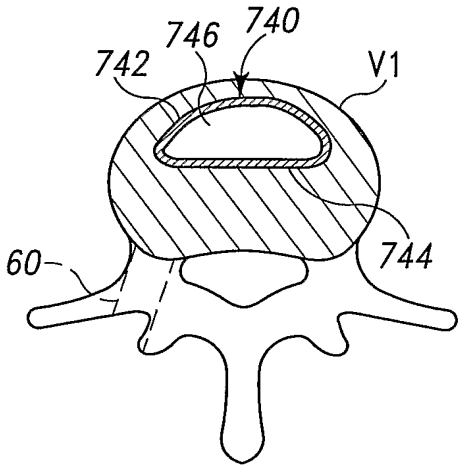

Fig. 37A

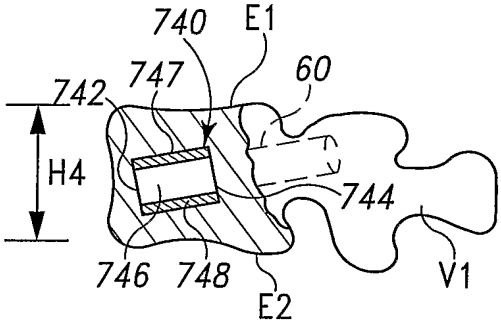

Fig. 37B

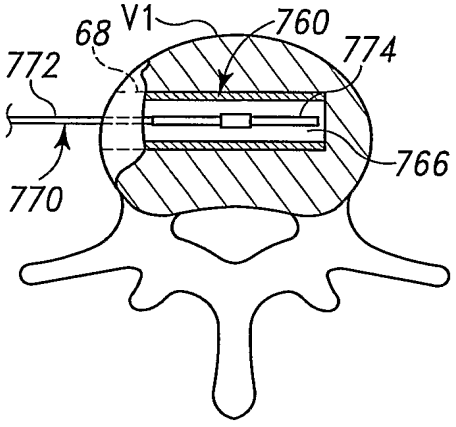

Fig. 38A

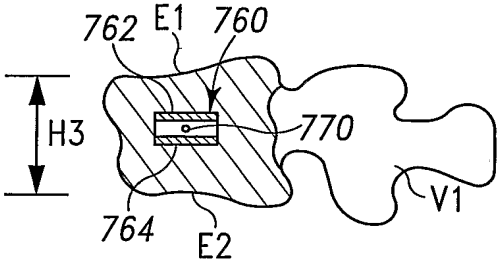

Fig. 38B

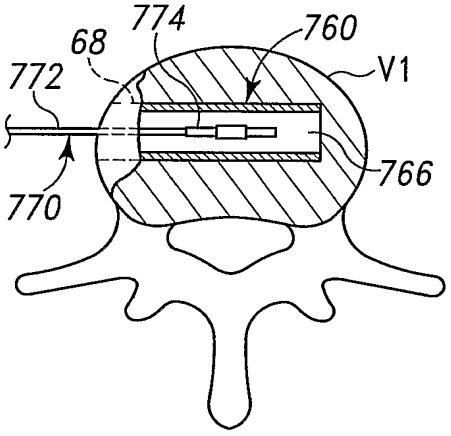

Fig. 39A

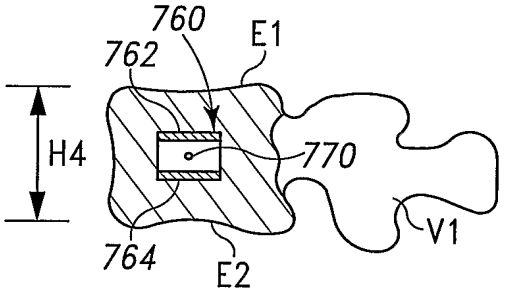

Fig. 39B

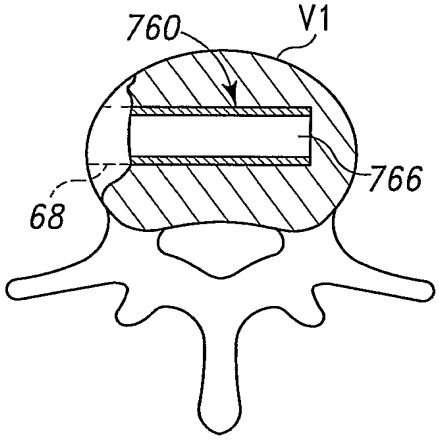

Fig. 40A

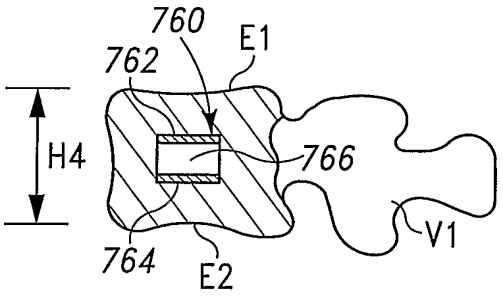

Fig. 40B

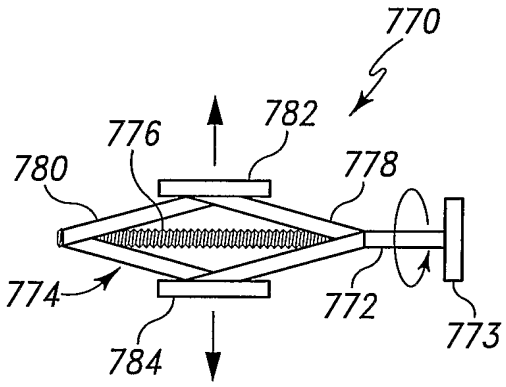

Fig. 41A

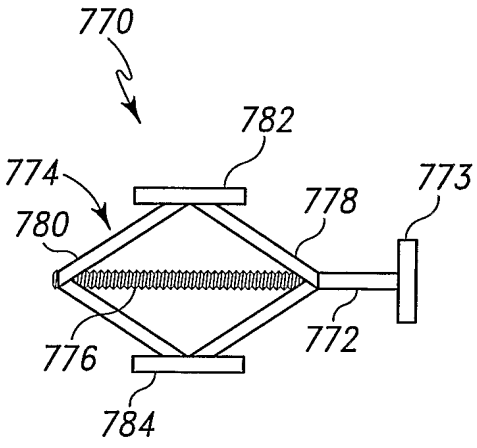

Fig. 41B

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 03/36951

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/30 A61F2/46 A61F2/44

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ, WPI Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 44319 A (GLOBERMAN OREN ;SHAVIT RONEN (IL); SHENHAV BOAZ (IL); DISC O TECH) 3 August 2000 (2000-08-03) page 21, line 23 -page 26, line 35 page 37, line 26 -page 47, line 28; claims 65,69 ---	37-43, 47-49, 53, 55-57, 61,62, 64,66
X	US 6 127 597 A (BEYAR MORDECHAY ET AL) 3 October 2000 (2000-10-03) column 27, line 18 -column 31, line 4; figures 6,7,11-13 --- -/--	37-43, 47-49, 52, 55-57, 61,62,64

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
5 April 2004	16/04/2004

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Lickel, A

INTERNATIONAL SEARCH REPORT

Int onal Application No
PCT/US 03/36951

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 00 35389 A (SUDDABY LOUBERT) 22 June 2000 (2000-06-22) page 5, line 15 -page 7, line 24; figures 1-3,6-11	37, 41-47, 49,52
X	US 6 190 414 B1 (YOUNG WAYNE P ET AL) 20 February 2001 (2001-02-20) column 4, line 23 -column 6, line 58; figures 3-10,13,14	37, 41-45, 47,50,51 63

INTERNATIONAL SEARCH REPORT

...rnational application No.
PCT/US 03/36951

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 1-36
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int[illegible]onal Application No
PCT/US 03/36951

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 0044319 A	03-08-2000	AU 2126800 A	18-08-2000
		AU 2316600 A	18-08-2000
		AU 2316700 A	18-08-2000
		EP 1153147 A1	14-11-2001
		EP 1148851 A2	31-10-2001
		EP 1148850 A1	31-10-2001
		WO 0044946 A1	03-08-2000
		WO 0044321 A2	03-08-2000
		WO 0044319 A1	03-08-2000
		JP 2002535080 T	22-10-2002
		JP 2002535081 T	22-10-2002
		JP 2002535109 T	22-10-2002
US 6127597 A	03-10-2000	WO 0044946 A1	03-08-2000
		WO 0154598 A1	02-08-2001
		AU 745916 B2	11-04-2002
		AU 6513698 A	22-09-1998
		CA 2283190 A1	11-09-1998
		EP 1011464 A1	28-06-2000
		WO 9838918 A1	11-09-1998
		JP 2001527437 T	25-12-2001
WO 0035389 A	22-06-2000	US 6183517 B1	06-02-2001
		US 6174334 B1	16-01-2001
		US 6159244 A	12-12-2000
		AU 2157300 A	03-07-2000
		EP 1139936 A1	10-10-2001
		JP 2002532145 T	02-10-2002
		WO 0035389 A1	22-06-2000
US 6190414 B1	20-02-2001	NONE	